BAKER BOTTS LLP

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/695,194
Filing Date	October 28, 2003
First Named Inventor	Hochstrasser
Group Art Unit	1645
Examiner Name	Swartz, Rodney P
Total Number of Pages in This Submission	
Attorney Docket Number	A36054-PCT-USA-A (072874.

ENCLOSURES *(check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [✓] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group (*Appeal Notice, Brief, Reply Brief*)
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) *(please identify below)*:

Return receipt postcard;

Remarks [ ]

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	BakerBotts LLP 30 Rockefeller Plaza New York, NY 10112
Signature	Rochelle K. Seide — Att Name: Rochelle K. Seide; PTO Reg: 32,300
Date	January 20, 2005

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: January 20, 2005

Typed or printed name	Rochelle K. Seide		
Signature	Rochelle K. Seide	Date	January 20, 2005

BAKER BOTTS LLP

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 0

Complete if Known	
Application Number	10/695,194
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Examiner Name	Swartz, Rodney P
Art Unit	1645
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METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number: 02-4377

Deposit Account Name: Baker Botts LLP

The Commissioner is authorized to: *(check all that apply)*

☑ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee required under 37CFR 1.16 and 1.17

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below	Fee Paid
Total Claims		- 20 =	0	X		0
Independent Claims		- 3 =	0	X		0
Multiple Dependent						

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	0
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0

SUBMITTED BY				(Complete *if applicable*)	
Name (Print/Type)	Rochelle K. Seide	Registration No. (Attorney/Agent)	32,300	Telephone	212 408 2626
Signature	Rochelle K. Seide			Date	January 20, 2005

BAKER BOTTS LLP

Attorney Docket Number: A36054-PCT-USA-A (072874.

Title: DIAGNOSTIC METHOD FOR TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

Use Space Below for Additional Information:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s)	:	Hochstrasser et al.
Serial No.	:	10/695,194
For	:	DIAGNOSTIC METHOD FOR TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
Filed	:	October 28, 2003
Examiner	:	Swartz, Rodney P
Art Unit	:	1645

RESPONSE TO RESTRICTION REQUIREMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

January 20, 2005
Date of Deposit

Rochelle K. Seide
Attorney Name

32,300
Registration No.

Signature

January 20, 2005
Date of Signature

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Office Communication dated December 20, 2004 in the above-identified application. Since the Applicants have filed this response within the shortened statutory period for reply of one month, this paper is timely filed. Applicants therefore believe that no fee is due in the submission of this paper.

The Examiner has issued a restriction requirement under 35 U.S.C. §121 and requires selection of one of six groups of claims for prosecution in this application:

Group I: Claims 1-19, 21, 22 and 29-46, drawn to method and kit for diagnosis of TSE by detecting polypeptide;

Group II: Claim 20, drawn to method for diagnosis of TSE by detecting antibody;

Group III: Claim 20, drawn to therapy using polypeptide;

Group IV: Claims 21 and 22, drawn to therapy using antibody;

Group V: Claims 23-28, drawn to device using antibody; and

Group VI: Claim 47, drawn to normal bovine animals.

The Examiner asserts that the inventions of Group I and II are drawn to two distinct methods. The Examiner alleges that the invention of Group I is a method for detecting polypeptides while Invention II is a method for detecting antibodies.

The Examiner alleges that the inventions of Group I and III are drawn to two distinct methods, namely for the diagnosis of disease or a method of therapy respectively.

The Examiner alleges that inventions of Group I and IV are drawn to two distinct methods using different reagents. The claims of Group I are allegedly drawn to a method of detecting disease by detecting polypeptides while claims of Group IV are drawn to a method of therapy for infected hosts utilizing antibodies.

The claims of Group I and IV are allegedly distinct since it can be shown that the process as claimed can be performed by another with a materially different apparatus. The Examiner alleges that the process of Invention I can be performed with a materially different apparatus i.e. by mass spectrometry.

It is alleged by the Examiner that the claims of Groups I and VI are drawn to patentably distinct inventions since Invention I is a method for diagnosis of disease while Invention IV is a normal bovine animal.

The Inventions of Groups I and IV, Groups II and III and Groups II and III are allegedly drawn to different methods utilizing different reagents and having different end results.

The Examiner alleges that the inventions of Groups II and V are drawn to different methods and device. Claims of Invention II are drawn to a method of diagnosis by detecting antibody while Invention V is a device with bound antibody for detecting polypeptides.

The Examiner alleges that the claims of Groups II and VI are drawn to patentable distinct inventions wherein Invention II is a method for diagnosis and Invention VI is a normal bovine animal.

The Examiner alleges that the claims of Groups III and IV are drawn to different methods, utilizing different reagents and different method steps.

Invention III and V are allegedly drawn to structurally and functionally distinct inventions wherein claims of Invention III is drawn to polypeptides while claims of invention V is a device with bound antibody.

The Inventions of Groups III and VI are allegedly patentably distinct inventions. Group III is allegedly a method of therapy and Group VI is a normal bovine animal.

The Examiner alleges that the claims of Groups IV and V are drawn to different methods which utilize different reagents and method steps.

The Examiner alleges that the claims of Groups IV and VI are drawn to patentably distinct inventions. Group IV is a method of therapy and Group VI is a normal bovine animal.

The Examiner alleges that the claims of Groups V and VI are drawn to structurally and functionally distinct products. Invention V is a device and Invention VI is a normal bovine animal.

Furthermore, the Examiner alleges that the inventions have separate status in the art due to their different classification. The Examiner further allege that in instances where the classification are the same, the non-patent literature searches are not co-extensive, causing the searches to be burdensome.

Applicants respectfully traverse. There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP § 802.01, § 806.04 and § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) There must be a serious burden on the Examiner if restriction is required (see MPEP § 808.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). The term "independent" (*i.e.*, not dependent) means that there *is no disclosed relationship* between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect. (Emphasis supplied, MPEP § 802.01). Moreover, MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner *must* examine it on the merits, even though it contains claims to distinct or independent inventions." (Emphasis supplied).

Applicants submit that the inventions of Group I are clearly connected to Groups II and III. All three groups comprise of a method of diagnosis (Claims 1-19, 20, 21, 22, 29-46) prognosis or therapy (Claims 20-22) of transmissible spongiform encephalopathy (TSE) or related conditions by detecting or utilizing a polypeptide differentially contained in the body fluid of TSE-infected subjects. The inventions of Group IV and V are clearly connected to the invention of Groups I, II and III. The steps comprising the method recited in the claims of Group I, II and III form the basis of the inventions of Group IV and V. Applicants submit that the "assay device for use in diagnosis" as recited in claims of Group V, encompasses the invention of Groups I to IV. The claim of Group VI is dependent from claim 43 (Group I). The applicants submit that method

of diagnosis of claim 43 shares a common goal with the invention of Group VI in establishing the disease status of a set of subjects on which such testing is performed.

In conclusion, Applicant asserts that the claims of Groups I-VI are connected by a disclosed relationship and, therefore, should be examined together. Applicants further submit that the claims are connected by a single, searchable unifying relationship, and that the Examiner would not, therefore, be seriously burdened by searching and examining the claims of these groups in a single application. Accordingly, Applicants request withdrawal of the restriction requirement.

Under 37 C.F.R. §1.143 the applicants are required to reply to the Restriction Requirement by including an election of the invention to be examined. Applicants elect Group I, consisting of Claims 1-19, 21, 22 and 29-46 drawn to method and kit for diagnosis of TSE by detecting polypeptide, classified in class 436, subclass 501. Applicants submit that the election is made without prejudice to the prosecution of the subject matter of non-elected claims in divisional, continuation and continuation-in-part applications.

Applicants do not believe that any additional fee is required in connection with the submission of this document. Should any additional fees be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account 02-4377. A duplicate copy of this communication is provided.

Respectfully submitted,

BAKER BOTTS L.L.P.

By: 

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